'Walsh Medical Devices Inc.
1209 North Service Rd., E., Oakville, Ont., L6H1A7
Telephone: 905-844-8344 Fax: 905-338-0488

October 06, 1999

Dockets Management Branch
(HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland USA
20852

Re: Federal Register Vol. 64, No. 93 Friday, May 14, 1999
Foreign Establishment Registration and Listing
Docket Number 98N-1215

We are a small Canadian medical device manufacturer located in Oakville, Ontario, Canada. The United States represents a significant market for our products. We are concerned that the proposed amendments described in the federal register cited above will have a significant negative impact on our business.

We do not object to the requirement for foreign establishments to register with the FDA. In fact we are currently registered with the FDA and our products sold in the US are registered with the FDA. We've been subject to onsite FDA inspections and stand ready to comply with the requirements which the US government has implemented for medical devices sold in the US. In this we appreciate that we are considered on equal basis with any US- based manufacturer.

We're extremely concerned with the requirement that would have us designate a United States agent to represent us to the FDA. When a US designated agent was first discussed a few years ago the cost for representation of a company exporting a single product to the US was in the area of $6,000 to $10,000 per year. We assume the high cost reflects concerns regarding potential liability in dealing with medical products. This cost would be a significant burden to a company such as ours and rather than expediting and clarifying communications between us and the FDA would in all probability result in delays and confusion. Because of the proximity of our company to the US and the fact that we share language time zones it is likely that the FDA can communicate with us as easily has any domestic US manufacturer,

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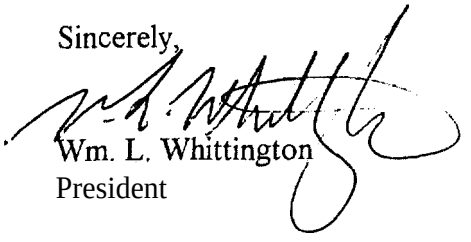
We trust these comments will be taken into consideration and hope that the FDA can find a way to avoid requiring that Canadian suppliers of medical devices be required to hire a United States agent to represent them to the FDA.

Sincerely,



Wm. L. Whittington
President

ELIZABETH ARCHER
WALSH MEDICAL DEVICES INC
Phone: 905-844-8344
1209 NORTH SERVICE RD E
OAKVILLE
ON L6H1A7
CANADA

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